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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,686	07/10/2006	David Edmund Wright	MKC-001	2900

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EXAMINER	
MUI, CHRISTINE T	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,686	WRIGHT, DAVID EDMUND	
	Examiner	Art Unit	
	CHRISTINE T. MUI	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 32-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30 and 32-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *18 August 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because: There are two Figures 2a submitted on 24 January 2006. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: S400. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid

abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 4 and 9 recites the broad recitation 0.8 for the correlation coefficient, and the claim also recites 0.3 as the correlation coefficient parameter which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 28, 29 and 39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims are not patentable under 35 USC 101 because the carrier may be either an optical or electrical signal carrier as described in the specification on page 10.

Claim 30 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claim is not of patentable subject matter because computer programs are functional descriptive material and this type of material is not, *per se*, eligible. 33 F.3d at 1360, 31 USPQ2d at 1759, MPEP 2106.01

Claims 1-4, 7-9, 13-17, 19-27, and 33-38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The methods of the instant claims must meet a specialized, limited meaning to qualify as a patent-

eligible process claim. The test is whether the claimed method is (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. A machine is a "'concrete thing, consisting of parts, or of certain devices and combination of devices.' This 'includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. In re Nuijten, 500 F.3d 1346 (Fed. Cir. 2007). The Court stated in Bilski, "[p]urported transformations or manipulations simply of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances." 545 F.3d at 963.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-11, 13-26, 28-30 and 32-39 rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 800 085 to Davies (submitted on the Information Disclosure Statement on 18 August 2006; herein referred 'Davies').

10. Regarding claim 1-3, 5-8, 10-11, 13-26, 28-30 and 32-39 , the reference Davies discloses a method for antenatal screening for an abnormality in a fetus of a woman. The screening is determined using a bodily fluid, the fluid containing a marker at which at one stage of a gestation (stage A) and another stage of gestation (stage B). Stage A is the mean or median level of the marker differs by less than 20% between pregnancies which are affected and unaffected by the abnormality and Stage B marker differs by more than 50% between affected and unaffected pregnancies and a computer is provided for the means for comparing the measurements of the levels with each other and to sets of reference data to determine fetal abnormalities characterized in that the computer is capable of comparing concentrations. There is at least 3 weeks between Stage A and Stage B. The concentrations of the marker for an individual women are made at Stage A and Stage B and are compared and a normalized concentration is determined and compared with similarly determined normalized concentrations. The serum marker that is identified in the samples are intact hCG or the free alpha or beta subunits of hCG as well as AFT, PAPP-A, dimeric inhibin (inhibin A) and Schwangerschaft protein (Pregnancy specific X-glycoprotein 1, SP1). In determining the likelihood of a chromosomal abnormality it is know that some markers are lower in concentration at particular stages, for example PAPP-A are known to be lower in the

first trimester where the fetus has Down Syndrome, yet show no difference in the second trimester of pregnancy. The measurements are carried out and analyzed using the method of invention on samples taken during an appropriate period of pregnancy. The measurements are taken in the first and second trimesters and often in the period between the beginning of the eighth week and the end of the second trimester. The concentrations of most maternal serum markers change during pregnancy as a result of changes in the size and maturity of the fetus or placenta and in order to enable valid comparisons between the concentrations at different stages of pregnancy, they must be normalized by dividing the actual value by the median value found in the unaffected population of pregnant women at that gestational age (the Multiple of the Median or MoM). The median is used to avoid any undue influence of outlying values. The serum value for the individual serum marker is divided by the normalized expected median value found in women with unaffected pregnancies at the same gestation age to derive the multiple of the median (MoM). The probability that the (MoM) values for the markers belongs to the multivariate distribution of values found in unaffected pregnancies is calculated. The same calculation is performed by reference to the probability that the individual combination of values forms part of the multivariate distribution found in abnormal pregnancies. The ratio of the probabilities is termed the likelihood ratio that indicates the likelihood that an individual woman has an affected pregnancy or not. The degree of separation between the multivariate distributions for affected and unaffected pregnancies changes with gestational age, i.e. there is a continuous change in the

manner of calculating probability depending on the gestational age, and this change can be accounted for by an algorithm used in the calculation.

11. Davies does not specifically calculate the correlation between the two different stages, Stage A and Stage B; first trimester and second trimester, Davies does disclose that as seen in Figure 1, the median hCG concentration was determined at different weeks of gestation and the correlation is implied since both high values at stages or low values at stages is an indication of the risk for fetal Down Syndrome on account of the hCG concentration (see page 3, lines 1-55, page 4, lines 1-6, 40-56, Figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the calculation between all the marker concentrations to determine a marker concentration between two different stages, to determine the change in concentration at different stages of gestation to determine the risk of a chromosomal abnormality, since the same marker will eventually be chosen.

12. Regarding claims 4 and 9, the reference Davies discloses the claimed invention except for the specific correlation parameter, but it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the correlation coefficient without undue experimentation to select markers with a correlation between the first and second measurements since there are many markers to choose from to create a parameter for determine the risk of a chromosomal abnormality.

13. Claims 12 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies as applied to claims 1 and 20 above, and further in view of Benattar et al

(submitted on the Information Disclosure Statement on 18 August 2006; herein referred 'Benattar').

14. Regarding claims 12 and 27, the reference Davies discloses the claimed invention except for where the data is obtained from an ultrasound. Davies discloses obtaining the serum marker concentrations from maternal body fluids, for example, saliva, urine, amniotic fluid and blood (see page 4, lines 7-8). Benattar discloses that it is known in the art to obtain data of a marker from an ultrasound scan during the first trimester when determining whether or not the fetus has a chromosomal abnormality by measuring the Nuchal translucency thickness(see abstract, page 113). It would have been obvious to one having ordinary skill in the art at the time the invention was made to determiner the serum marker concentration data by a topical technique such as an ultrasound rather than an invasive procedure by drawing blood, to obtain a better detection rate and less false positives as suggested by Benattar in the abstract.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USP 5,906,944 to Davies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797